



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Attorney Docket No.: DRE-0067

Inventors: Laurencin et al.

Serial No.: 10/052,121

Filing Date: January 17, 2002

Examiner: Not Yet Assigned

Group Art Unit: 1636

Title: Biocompatible, Biodegradable Polymer-Based, Lighter Than or Light as Water Scaffolds for Tissue Engineering and Methods for Preparation and Use Thereof

I, **Kathleen A. Tyrrell**, Registration No. **38,350**, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

On this date: April 1, 2002


Kathleen A. Tyrrell, Registration No. 38,350

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
 - () Certification in Accordance with §1.97(e) is set forth below; or
 - () The fee of \$180.00 as set forth in §1.17(p) is attached.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith with the exception of AB. In view of the voluminous nature of this publication and the likelihood that the Examiner may have a copy available to him or her, a copy has not been included herewith. However, if the Examiner does not have a copy

available, Applicant will endeavor to supply one at the Examiner's request.

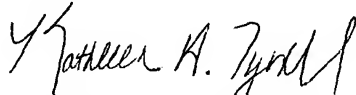
- () In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

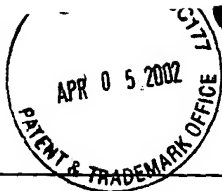


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Date: April 1, 2002

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Sheet 01

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| Form PTO-1449 Modified | | Docket No. DRE-0067 | Serial No. 10/052,121 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant Laurencin et al. | |
| | | Filing Date January 17, 2002 | Group 1636 |
| U.S. Department of Commerce | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | AA | Becker et al., "Three-Dimensional Growth and Differentiation of Ovarian Tumor Cell Line in High Aspect Rotating-Wall Vessel: Morphologic and Embryologic Considerations", <i>J. Cellular Biochem.</i> 1993 51(3):283-289 | |
| | AB | Burwell R.G. Bone Grafts, Derivatives and Substitutes., M.R. Urist and R.G. Burwell, Editors 1994, Butterworth-Heinemann Ltd.: Oxford | |
| | AC | Casser-Bette et al., "Bone Formation by Osteoblast-Like Cells in a Three-Dimensional Cell Culture", <i>Calcified Tissue International</i> 1990 46:46-56 | |
| | AD | Cook et al., "The Effect of Recombinant Human Osteogenic Protein-1 on Healing of Large Segmental Bone Defects" <i>J. Bone Joint Surg. Am.</i> 1994 76(6):827-838 | |
| | AE | Devin et al., "Three-dimensional degradable porous polymer-ceramic matrices for use in bone repair", <i>J. Biomater. Science-Polymer Edition</i> 1996 7(8):661-669 | |
| | AF | Ducheyne et al., "Effect of Bioactive Glass Templates on Osteoblast Proliferation and In Vitro Synthesis of Bone-Like Tissue", <i>J. Cell. Biochem.</i> 1994 56:162-167 | |
| | AG | El-Ghannam et al., "Bioactive material template for <i>in vitro</i> synthesis of bone" <i>J. Biomed. Mater. Res.</i> 1995 29:359-370 | |
| | AH | Gadzag et al., "Alternatives to Autogenous Bone Graft: Efficacy and Indications", <i>J. Amer. Acad. Ortho. Surg.</i> 1995 3(1):1-8. | |
| | AI | Goldstein et al., "Effect of Osteoblastic Culture Conditions on the Structure of Poly(DL-Lactic-co-Glycolic Acid) Foam Scaffolds", <i>Tissue Engineering</i> 1999 5(5):421-433 | |
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| Form PTO-1449 Modified | | Docket No. DRE-0067 | Serial No 10/052,12 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant Laurencin et al. | |
| | | Filing Date January 17, 2002 | Group 1636 |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | AJ | Granet et al., "Rotating-wall vessels, promising bioreactors for osteoblastic cell culture: comparison with other 3D conditions", <i>Cell Eng.</i> 1998 3:513-519 | |
| | AK | Ishaug et al., "Bone formation by three-dimensional stromal osteoblast culture in biodegradable polymer scaffolds", <i>J. Biomed. Mater. Res.</i> 1997 36:17-28 | |
| | AL | Ishaug-Riley et al., "Three-dimensional culture of rat calvarial osteoblasts in porous biodegradable polymers", <i>Biomaterials</i> 1998 19:1405-1412 | |
| | AM | Klement and Spooler, "Utilization of Microgravity Bioreactors for Differentiation of Mammalian Skeletal Tissue", <i>J. Cellular Biochem.</i> 1993 51:252-256 | |
| | AN | Labarca and Paigen, "A Simple, Rapid, and Sensitive DNA Assay Procedure", <i>Anal. Biochem.</i> 1980 102:344-352 | |
| | AO | Langer and Vacanti, "Tissue Engineering", <i>Science</i> 1993 260(5110):920-926 | |
| | AP | Laurencin et al., "Tissue Engineered Bone-Regeneration Using Degradable Polymers: The Formation of Mineralized Matrices", <i>Bone</i> 1996 19(1):93S-99S | |
| | AQ | Laurencin et al., "A highly porous 3-dimensional polyphosphazene polymer matrix for skeletal tissue regeneration", <i>J. Biomed. Mater. Res.</i> 1996 30:133-138 | |
| | AR | Lewis et al., "Use of Microgravity Bioreactors for Development of an In Vitro Rat Salivary Gland Cell Culture Model", <i>J. Cellular Biochem.</i> 1993 51:265-273 | |
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Sheet 03



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| Form PTO-1449 Modified | | Docket No. DRE-0067 | Serial No. 10/052,121 |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | AS | Masi et al., "Adhesion, Growth, and Matrix Production by Osteoblasts on Collagen Substrata", <i>Calcified Tissue International</i> 1992 51:202-212 | |
| | AT | Mizuno et al., Osteogenesis by Bone Marrow Stromal Cells Maintained on Type I Collagen Matrix Gels In Vivo", <i>Bone</i> 1997 20(2):101-107 | |
| | AU | Prewett et al., "Three-Dimensional Modeling of T-24 Human Bladder Carcinoma Cell Line: A New Simulated Microgravity Culture Vessel", <i>J. Tissue Culture Methods</i> 1993 15:29-36 | |
| | AV | Qui et al., "Formation and Differentiation of Three-Dimensional Rat Marrow Stromal Cell Culture on Microcarriers in a Rotating-Wall Vessel", <i>Tissue Engineering</i> 1998 4(1):19-34 | |
| | AW | Rattner et al., "Characterization of Human Osteoblastic Cells: Influence of The Culture Conditions", <i>In Vitro Cellular & Developmental Biology-Animal</i> 1997 33:757-762 | |
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| | AZ | Van Belle H., "Kinetics and Inhibition of Alkaline Phosphatases from Canine Tissues", <i>Biochimica et Biophysica Acta</i> 1972 289:158-168 | |
| | BA | Wu and Forsling, "Potentiometric and Spectrophotometric Study of Calcium and Alizarin Red S. Complexation", <i>Acta Chemica Scandinavica</i> 1992 46:418-422 | |
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